Initial REMS Approval: 02/06/2013

Most Recent Modification: XX/XX/XXXX

NDA 203479

Versacloz™ (clozapine) oral suspension

Class of Product: Atypical Antipsychotic

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VERSACLOZ™ RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

To minimize the risk of agranulocytosis associated with the use of Versacloz by:

- Ensuring compliance with the monitoring schedule for White Blood Cell Count (WBC) and Absolute Neutrophil Count (ANC) prior to dispensing Versacloz
- Preventing re-exposure of patients who have previously experienced agranulocytosis or severe granulocytopenia/leukopenia with any clozapine products.

II. REMS ELEMENTS

A. Elements To Assure Safe Use

1. Healthcare providers who prescribe Versacloz are specially certified.

a. Jazz Pharmaceuticals International III (henceforth, "Jazz Pharmaceuticals") will ensure that healthcare providers who prescribe Versacloz are specially certified.
b. The healthcare provider enrollment process comprises the following steps that must be completed prior to prescribing Versacloz:
    i. The healthcare provider completes the Healthcare Provider Enrollment Form. In signing the Healthcare Provider Enrollment Form, each healthcare provider indicates they understand that clozapine is available only through the Versacloz REMS Program, entitled Versacloz Patient Registry, and are aware of and attest to the following requirements:
        a) Review the Versacloz package insert and understand the risk of death associated with agranulocytosis or severe granulocytopenia/leukopenia when prescribing Versacloz.
        b) Enroll all applicable patients in the Versacloz Patient Registry. When enrolling a patient, healthcare providers will be matched with an enrolled pharmacy and be defined as an "affiliated treatment pair" by completing the appropriate section of the Patient Enrollment Form.
        c) Understand the recommendations for prescribing and monitoring as described in the Versacloz package insert.
        d) Understand Versacloz should only be prescribed to new patients after verifying an acceptable baseline WBC count (≥3500/mm3) and ANC (≥2000/mm3) test results, submitting the Patient Registration Form with baseline labs within 7 days of blood draw and only after receiving a Patient Registration Number (PRN) from the Versacloz Patient Registry.
        e) Understand that no more than a 7 day supply of Versacloz should be prescribed to a patient who has been continually on clozapine treatment with a different clozapine formulation (i.e. clozapine tablets, clozapine orally disintegrating tablets) prior to initiating Versacloz but who is not currently enrolled in the Versacloz Patient Registry, and understand that Versacloz should not be prescribed in such circumstances until verification that the patient has an acceptable baseline WBC count (≥3500/mm3) and ANC

(≥2000/mm3). They understand they should prescribe Versacloz to a patient a second time only after receiving a valid PRN from the Versacloz Patient Registry

f) Complete the Patient WBC Count and ANC Monitoring Form and provide the affiliated pharmacist with the completed form and a valid prescription for each dispensation of Versacloz.

g) Follow the process for a patient discontinued from Versacloz, regardless of the reason for discontinuation:
   i. Indicate discontinuation of Versacloz on the Patient WBC Count and ANC Monitoring Form
   ii. Notify the Versacloz Patient Registry by submitting the completed Patient WBC Count and ANC Monitoring Form to the Versacloz Patient Registry.
   iii. Notify the affiliated pharmacy by submitting the completed Patient WBC Count and ANC Monitoring Form to the affiliated pharmacy
   iv. Submit the required WBC count and ANC test results to the Versacloz Patient Registry weekly for at least 4 weeks from the day of discontinuation or until the patients labs return to normal (WBC>3500mm3 and ANC>2000/mm3).

h) Understand the list of patients enrolled in the Versacloz Patient Registry will be used to verify the patient's rechallenge status against the Clozapine National Non-Rechallenge Masterfile. Furthermore, any patient permanently discontinued from Versacloz for meeting the non-rechallenge criteria (WBC count <2000/mm^3 and/or ANC <1000mm^3) will be reported to the Clozapine National Non-Rechallenge Masterfile. .

i) Understand the Versacloz Patient Registry will be audited to monitor adherence to prescribing and monitoring requirements, and enrolled healthcare providers and pharmacies will be promptly notified of any discrepancies or missing information by Jazz Pharmaceuticals.

c. Jazz Pharmaceuticals will:
   i. Ensure that healthcare provider enrollment can successfully be completed via the Versacloz REMS website, or by mailing or faxing the forms.
   ii. Ensure that, as part of the enrollment process, the following materials that are part of the Versacloz REMS program are available to healthcare providers. These materials are appended:
      - *Healthcare Provider Enrollment Form*
   iii. Ensure that the *Healthcare Provider Enrollment Form* is complete before a healthcare provider's enrollment is activated in the Versacloz REMS program.
   iv. Ensure that healthcare providers are notified when they are successfully enrolled in the Versacloz REMS program, and therefore, are certified to prescribe Versacloz.

v. Monitor enrollment requirements for healthcare providers and institute corrective action and/or inactivate non-compliant healthcare providers. Upon initial activation, healthcare providers remain active until inactivation occurs.

2. Pharmacies that dispense Versacloz are specially certified.

a. Jazz Pharmaceuticals will ensure that pharmacies that dispense Versacloz are specially certified.
b. The pharmacy enrollment process comprises the following steps that must be completed prior to dispensing Versacloz:
    i. The lead pharmacist will complete the Pharmacy Enrollment Form. In signing the Pharmacy Enrollment Form, the lead pharmacist indicates that all pharmacists with dispensing privileges at the pharmacy understand that Versacloz is only available to certified pharmacies after enrolling in the Versacloz REMS program, entitled Versacloz Patient Registry, and are aware of and attest to the following requirements:
        a) Review the Versacloz package insert and understand the risk of death associated with agranulocytosis or severe granulocytopenia/leukopenia prior to dispensing Versacloz.
        b) Enroll all applicable patients in the Versacloz Patient Registry. When enrolling a patient, healthcare providers will be matched with an enrolled pharmacy and be defined as an "affiliated treatment pair" by completing the appropriate section of the *Patient Enrollment Form*.
        c) Understand the recommendations for prescribing and monitoring as described in the package insert.
        d) Understand Versacloz should only be dispensed to a new patient after verifying an acceptable baseline WBC count (≥3500/mm3) and ANC (≥2000/mm3) test results and only after receiving a Patient Registration Number (PRN) from the Versacloz Patient Registry.
        e) Understand that no more than a 7 day supply of Versacloz should be dispensed to a patient who has been continually on clozapine treatment with a different clozapine formulation (i.e. clozapine tablets, clozapine orally disintegrating tablets) prior to initiating Versacloz but is not currently enrolled in the Versacloz Patient Registry, and understand that Versacloz should not be dispensed in such circumstances until verification that the patient has an acceptable baseline WBC count (≥3500/mm3) and ANC (≥2000/mm3). They understand they should dispense Versacloz to a patient a second time only after receiving a valid PRN from the Versacloz Patient Registry.

f) Understand the importance of providing the Versacloz Patient Registry with all WBC count and test results for all enrolled patients within:
- 7 days from blood draw to patients on weekly monitoring schedule
- 14 days from blood draw to patients on bi weekly monitoring schedule
- 28 days from blood draw to patients on monthly monitoring schedule

g) Understand the list of patients enrolled in the Versacloz Patient Registry will be used to verify a patient's rechallenge status against the Clozapine National Non- Rechallenge Masterfile. Furthermore, any patient permanently discontinued from Versacloz for meeting the non-rechallenge criteria (WBC count <2000/mm^3 and/or ANC<1000mm^3) will be reported to the Clozapine National Non-Rechallenge Masterfile.

h) Understand the Versacloz Patient Registry will be audited to monitor adherence to prescribing, monitoring and timeliness requirements and enrolled healthcare providers and pharmacies will be promptly notified of any discrepancies or missing information by Jazz Pharmaceuticals.

c. Jazz Pharmaceuticals will:
   i. Ensure that pharmacy enrollment can successfully be completed via the Versacloz REMS website, or by mailing or faxing the forms.
   ii. Ensure that, as part of the enrollment process, the following materials that are part of the Versacloz REMS program are available to pharmacies. These materials are appended:
      - *Pharmacy Enrollment Form*
   iii. Ensure that the *Pharmacy Enrollment Form* is complete before a pharmacy's enrollment is activated in the Versacloz REMS program.
   iv. Ensure that pharmacies are notified when they are successfully enrolled in the Versacloz REMS program, and therefore, are certified to dispense Versacloz.
   v. Monitor enrollment requirements for pharmacies/pharmacists and institute corrective action and/or inactivate non- compliant pharmacies/pharmacists. Upon initial activation, pharmacies/pharmacists remain active until inactivation occurs.

3. **Versacloz may be dispensed to patients with documentation of safe-use conditions.**

a. Jazz Pharmaceuticals will ensure that no patient is able to be enrolled with the Versacloz Patient Registry or provided a PRN if the patient is in the Clozapine National Non-Rechallenge Masterfile to assure safe-use conditions.
   i. Jazz Pharmaceuticals will ensure that the following will be completed upon receipt of the completed patient enrollment form:

a) Review the form for completeness and clarity.
b) Verify that the patient is not included in the Clozapine National Non- Rechallenge Masterfile.
c) Confirm that the patient's WBC count and ANC test results, which have been obtained within 1 week of the registration date, are acceptable (WBC count $\geq 3500/mm^3$ and ANC $\geq 2000/mm^3$.)
d) Notify the pharmacist of patient non-rechallenge and registration status and provide a PRN by mail, fax, or e-mail.
e) Separately notify the patient's healthcare provider of the patient's non- rechallenge status and his/her PRN by mail, fax, or e-mail.
f) Provide notification of monitoring schedule when appropriate data are available to the registry.

ii. Jazz Pharmaceuticals will ensure that, as part of the enrollment process, the following enrollment form that is part of the Versacloz REMS program is available to enrolled healthcare providers and pharmacies. These materials are appended:
- *Patient Enrollment Form*

4. Each patient using Versacloz is subject to certain monitoring.

a. Jazz Pharmaceuticals will ensure that required routine laboratory results (WBC and ANC) are received from enrolled healthcare providers and pharmacies according to the patient's appropriate monitoring schedule as described in the Versacloz package insert.
   i. Jazz Pharmceuticals will ensure that the *Patient WBC Count and ANC Monitoring Form* can successfully be completed via the Versacloz REMS website, by phone, or by mailing or faxing the forms.
   ii. Jazz Pharmaceuticals will ensure that, as part of the monitoring process, the following materials that are part of the Versacloz REMS program are available to enrolled healthcare providers and pharmacies. These materials are appended:
      - *Single Patient WBC Count and ANC Monitoring Form*
      - *Multiple Patient WBC Count and ANC Monitoring Form*
b. Jazz Pharmaceuticals will ensure that any patient for which they receive confirmed blood test results that meet the non-rechallenge criteria (WBC count below 2000/mm3 and/or ANC below 1000/mm3) will be reported to the Clozapine National Non-Rechallenge Masterfile within 48 hours.
c. Jazz Pharmaceuticals will ensure that certified healthcare providers submit WBC count and ANC values for any patient who experiences confirmed blood test results that meet the non-rechallenge criteria (WBC count below 2000/mm3 and/or ANC below 1000/mm3) until laboratory results return to normal (WBC>3500mm3 and ANC>2000/mm3) and for at least 4 weeks from day of discontinuation of therapy.

5. Each patient using Versacloz is enrolled in a registry.

a. Jazz Pharmaceuticals will ensure that certified healthcare providers enroll each patient in the Versacloz Registry. The registry will collect patient demographics, patient's affiliated treatment team (MD and RPh), all required routine labs (ANC and WBC), patient monitoring schedule (weekly, bi-weekly, monthly), and non-rechallengeable status.
b. Jazz Pharmaceuticals will ensure that the patient enrollment can successfully be completed via the Versacloz REMS website, by phone, or by mailing or faxing the forms.

D. Implementation System

1. Jazz Pharmaceuticals will maintain a database of all enrolled entities (healthcare providers, pharmacies, and patients) and will monitor and evaluate implementation of the Versacloz REMS program requirements.
2. Jazz Pharmaceuticals will monitor distribution data and prescription data to ensure that only enrolled healthcare providers are prescribing and enrolled pharmacies are dispensing Versacloz. Corrective action or inactivation will be instituted by Jazz Pharmaceuticals if non-compliance is found.
3. Audit the Versacloz Patient Registry to monitor adherence to prescribing and monitoring requirements and promptly notify enrolled healthcare providers and pharmacies of any discrepancies and obtain missing information.
4. Jazz Pharmaceuticals will maintain a call center to support patients, healthcare providers, pharmacies, and distributors in interfacing with the Versacloz REMS program.
5. Jazz Pharmaceuticals will ensure that all materials listed in or appended to the Versacloz REMS program will be available through the Versacloz REMS program website, www.versaclozregistry.com or by calling the Versacloz REMS call center at **1-877-329-2256**.
6. If there are substantive changes to the Versacloz REMS program, Jazz Pharmaceuticals will update all affected materials and notify pharmacies, prescribers, and distributors of the changes, as applicable. Notifications for patients will be sent to the patient's healthcare provider. Substantive changes to the Versacloz REMS program are defined as:
   - Significant changes to the operation of the Versacloz REMS program.
   - Changes to the package insert that affect the risk-benefit profile of Versacloz
7. Based on monitoring and evaluation of the REMS Elements to Assure Safe Use, Jazz Pharmaceuticals will take reasonable steps to improve implementation of these elements and to maintain compliance with the Versacloz REMS program requirements, as applicable.

E. Timetable for Submission of Assessments

Jazz Pharmceuticals will submit REMS Assessments to the FDA at a minimum, by 6 months, and annually thereafter from the date of approval of the REMS To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Jazz Pharmaceuticals

will submit each assessment so that it will be received by the FDA on or before the due date.

Versacloz™ Patient Registry **Healthcare Provider Enrollment Form**

Instruction: This form is used to enroll a healthcare provider in the Versacloz Patient Registry. Submitting this completed form indicated you have read and agree to the statement of OBLIGATIONS below. All forms must be signed and dated by the Healthcare Provider.

Healthcare Provider statement of OBLIGATIONS:

1. **I will review the Versacloz package insert and understand the risk of death associated with agranulocytosis when prescribing Versacloz**
2. **I will enroll all applicable patients in the Versacloz Patient Registry. When enrolling a patient, providers will be matched with an enrolled pharmacy and be defined as an "affiliated treatment pair" by completing the appropriate section of the Patient Enrollment Form.**
3. **I understand the recommendations for prescribing and monitoring as described in the package insert.**
4. **I understand Versacloz should only be prescribed to a new patient after verifying an acceptable baseline WBC count (≥3500/mm^3) and ANC (≥2000/mm^3) test results and only after receiving a Patient Registration Number (PRN) from the VersaCloz Patient Registry.**
5. **I understand that no more than a 7 day supply of VersaCloz should be prescribed to a patient who has been continually on clozapine treatment with a different clozapine formulation (i.e. clozapine tablets, clozapine orally disintegrating tablets) but is not currently enrolled in the VersaCloz Patient Registry, and understand that Versacloz should not be prescribed until verification that the patient has an acceptable baseline WBC count (≥3500/mm^3) and ANC (≥2000/mm^3). I understand I should prescribe Versacloz to a patient a second time only after receiving a Patient Registration Number (PRN) from the Versacloz Patient Registry.**
6. **I will complete the Patient WBC Count and ANC Monitoring Form and provide the affiliated pharmacist with the completed form and a valid prescription for each dispensation of Versacloz.**
7. **I will follow the process for a patient discontinued from Versacloz, regardless of the reason for discontinuation:**
   i. Indicate discontinuation of Versacloz on the Patient WBC Count and ANC Monitoring Form
   ii. Notify the VersaCloz Patient Registry by submitting the completed Patient WBC Count an ANC Monitoring Form to the Versacloz Patient Registry
   iii. Notify the affiliated pharmacy by submitting the completed Patient WBC Count and ANC Monitoring Form to the affiliated pharmacy.
   iv. Submit the required WBC count and ANC test results to the Versacloz Patient Registry weekly for at least 4 weeks from the day of discontinuation or until the patients labs return to normal (WBC>3500mm^3 and ANC>2000/mm^3)
8. **I understand the list of patients enrolled in the Versacloz Patient Registry will be used to verify the patient's rechallenge status against the Clozapine National Non-Rechallenge Masterfile. Furthermore, any patient permanently discontinued from Versacloz for meeting the non-rechallenge criteria (WBC<2000 mm^3 and/or ANC <1000mm^3) will be reported to the Clozapine National Non-Rechallenge Masterfile.**
9. **I understand the Versacloz Patient Registry will be audited to monitor adherence to prescribing, monitoring and timeliness requirements and registered healthcare providers and pharmacies will be promptly notified of any discrepancies or missing information by Jazz Pharmaceuticals,Inc.**

Healthcare Provider Signature	**Date:** (MM/DD/YYYY)

* The blood work draw date may not be more than 7 days old in order for the pharmacist to dispense the drug, regardless of the patients' monitoring schedule

Healthcare Provider Name (PLEASE PRINT)

Last:	**FIRST**	**M.I.**	**Suffix.**

Healthcare Provider ID # (optional)			-							

Medical Facility Information (Please Print)

Facility Name:		
Address:		
City:	**State:**	**Zip:**
Phone:	**Fax:**	**E-mail:**

Please answer the following question:

1. **Are you currently enrolled in any other clozapine registry?** **Yes** □ **No** □

If yes, please indicate the name of the registry:

Please mail or Fax completed form to:

Versacloz Patient Registry
1818 Market Street, Suite 2350
Philadelphia, PA 19103

Phone: 1-877-329-2256
Fax: 1-877-798-0229

Versacloz™ Patient Registry **Patient Enrollment Form**

Instruction: This form is used to register a patient in the Versacloz Patient Registry. Submitting this completed form indicates you have read and agree to the statement of OBLIGATIONS, have determined that Versacloz treatment is not contraindicated for this patient, and assigns one Healthcare Provider and one pharmacist as the Affiliated Treatment pair for this patient.

A. Patient Information:

Initials: (F/M/L)			**Birth Date:** (DD/MM/YYYY)		**Zip Code:**	

Patient Social Security | | | | - | | | - | | | | **Gender: Male** □ **Female** □

Race: **Caucasian** □ **African-American** □ **Asian** □ **Hispanic** □ **Other** □

Blood Draw Date: (MM/DD/YYYY)	**Dosage:**	**Total WBC Count (per mm^3)**	**ANC (per mm^3)**

QUESTIONS	Yes	No
1. Has the patient ever been treated with clozapine (brand or generic)?		
2. Is the patient currently enrolled in any other clozapine registry?		
3. Has the patient's clozapine treatment been interrupted in this time?		
4. Is the patient currently on every two weeks WBC count and ANC monitoring?		
5. Is the patient currently on every four weeks WBC count and ANC monitoring?		
6. If weekly WBC count and ANC monitoring, indicate how many weeks without treatment interruption since this treatment has started:		

B. Affiliated Treatment Pair Information: ***Only one Treatment Pair can be assigned by enrolled patient***

Healthcare Provider			**Pharmacy / Pharmacist**		
Name:			Name:		
ID# (optional):			DEA or ID#:		
Facility Name:			Pharmacy Name:		
Address:			Address:		
Phone:			Phone:		
Fax:			Fax:		
Email:			Email:		
Acknowledgement		**Date:**	**Acknowledgement**		**Date:**

Pharmacist: Once this form is received from the Affiliated Healthcare Provider this completed form should be mailed or Faxed to the:

Versacloz Patient Registry
1818 Market Street, Suite 2350
Philadelphia, PA 19103

Phone: 1-877-329-2256
Fax: 1-877-798-0229

Alternatively, the data may be phoned into the Registry at 1-877-329-2256 or the information may be entered into the Versacloz database via the internet at www.versaclozregistry.com

C. To be completed by the Registry Staff: DO NOT DISPENSE TREATMENT UNTIL Notified of Patient Eligibility with PRN

Patient Registration Number		**Assignment of PRN indicated that the registry staff has verified that this patient is not on the Clozapine National Non-Rechallenge Masterfile**

Versacloz™ Patient Registry **Pharmacy / Pharmacist Enrollment Form**

Instruction: This form is used to enroll a pharmacy / pharmacist in the Versacloz Patient Registry. Submitting this completed form indicated you have read and agree to the statement of OBLIGATIONS below. All forms must be signed and dated by the Pharmacist.

Pharmacy / Pharmacist statement of OBLIGATIONS:

I and all pharmacists with dispensing privileges at this pharmacy will:

1. **Review the Versacloz package insert and understand the risk of death associated with agranulocytosis prior to dispensing Versacloz.**
2. **Enroll all applicable patients in the Versacloz Patient Registry. When enrolling a patient, providers will be matched with an enrolled pharmacy and be defined as an "affiliated treatment pair" by completing the appropriate section of the Patient Enrollment Form.**
3. **Understand the recommendations for prescribing and monitoring as described in the VersaCloz package insert.**
4. **Understand VersaCloz should only be dispensed to a new patient after verifying an acceptable baseline WBC count (≥3500/mm^3) and ANC (≥2000/mm^3) test results and only after receiving a Patient Registration Number (PRN) from the Versacloz Patient Registry.**
5. **Understand that no more than a 7 day supply of VersaCloz should be dispensed to a patient who has been continually on clozapine treatment with a different clozapine formulation (i.e. clozapine tablets, clozapine orally disintegrating tablets) but is not currently enrolled in the VersaCloz Patient Registry, and understand that Versacloz should not be dispensed in such circumstances until verification that the patient has an acceptable baseline WBC count (≥3500/mm^3) and ANC (≥2000/mm^3). They understand they should dispense Versacloz to a patient a second time only after receiving a Patient Registration Number (PRN) from the Versacloz Patient Registry.**
6. **Understand the importance of providing the VersaCloz Patient Registry with all WBC count and test results for all enrolled patients within:**
   - **7 days from blood draw to patients on weekly monitoring schedule**
   - **14 days from blood draw to patients on bi weekly monitoring schedule**
   - **28 days from blood draw to patients on monthly monitoring schedule**
7. **Understand the list of patients enrolled in the Versacloz Patient Registry will be used to verify a patient's rechallenge status against the Clozapine National Non-Rechallenge Masterfile. Furthermore, any patient permanently discontinued from Versacloz for meeting the non-rechallenge criteria (WBC<2000 mm^3 and/or ANC <1000mm^3) will be reported to the Clozapine National Non-Rechallenge Masterfile.**
8. **Understand the Versacloz Patient Registry will be audited to monitor adherence to prescribing, monitoring and timeliness requirements and registered healthcare providers and pharmacies will be promptly notified of any discrepancies or missing information by Douglas Pharmaceuticals America Ltd.**

Pharmacist Signature	**Date** (MM/DD/YYYY)

* The blood work draw date may not be more than 7 days old in order for the pharmacist to dispense the drug, regardless of the patients' monitoring schedule

Pharmacist Name (PLEASE PRINT)

Last:	FIRST	M.I.	Suffix.

Pharmacy DEA or ID #

		-							

Pharmacy Information (Please Print)

Pharmacy Name:		
Address:		
City:	**State:**	**Zip:**
Phone:	**Fax:**	**E-mail:**

Please answer the following question:

1. **Is your pharmacy currently enrolled in any other clozapine registry?** **Yes** □ **No** □

If yes, please indicate the name of the registry:

Please mail or Fax completed form to:

Versacloz Patient Registry
1818 Market Street, Suite 2350
Philadelphia, PA 19103

Phone: 1-877-329-2256
Fax: 1-877-798-0229

Versacloz™ Patient Registry WBC Count and ANC Monitoring Form

Instructions: This form is used to submit WBC count and ANC monitoring information according to the Versacloz Patient Registry protocol and package insert. Multiple dates of information may be logged on one form for one patient if data submission is via fax. In this case, complete log and resubmit form every time according to schedule. Multiple forms will be required if data submission is via mail. NOTE: FORM MUST BE SUBMITTED TO REGISTRY AT EVERY DISPENSATION TIME.

- The patient's Affiliated Healthcare Provider must complete this form after verifying the patient's required blood counts are within normal limits and timeframe according to Versacloz product labeling and healthcare provider evaluates patient.
- The Affiliated Healthcare Provider must provide Affiliated Pharmacist with completed WBC Count and ANC Monitoring Form and valid prescription for each dispensation of Versacloz to meet monitoring requirements.
- The Affiliated Pharmacist can dispense Versacloz ONLY after receiving a completed WBC Count and ANC Monitoring Form with valid PRN, a valid prescription, and verifying the WBC count and ANC test results are within normal limits and timeframe according to Versacloz package insert.

A. Patient Information:

Initials: (F/M/L | | | |

Patient Registration Number (PRN): | | | | | |

Patient SSN: | | | | – | | | – | | | | |

B. Affiliated Pair Information (Patient's Affiliated Treatment Pair):

Healthcare Provider DEA or ID#: | | | – | | | | | | | |

Pharmacy DEA or ID#: | | | – | | | | | | | |

C. WBC Count, ANC, and Treatment Dispensation Information:

Blood Draw Date (MM/DD/YYYY)	Total WBC Count (per mm^3)	ANC (per mm^3)	Treatment Status After Today's Evaluation C=Continue T=TEMP Discontinue P=PERM Discontinue	Medication Dispense Date (MM/DD/YYYY)	Total Daily Dose (mg/day)	Acceptable to Dispense Treatment? Y = Yes N = No	Monitoring Schedule After Today's Evaluation		
							Weekly	Every Two Weeks	Every Four Weeks
Patient Notes									

Pharmacist: Once this form is received from the Affiliated Healthcare Provider this completed form should be mailed or FAXed to the

Versacloz Patient Registry
1818 Market Street, Suite 2350
Philadelphia, PA 19103

FAX: 1-877-798-0229

Alternatively, the data may be phoned into the Versacloz Patient Registry at 1-877-329-2256, or the information may be entered into the Versacloz database via the Internet at www.versaclozregistry.com

Versacloz™ Patient Registry

MULTI-PATIENT WBC Count and ANC Monitoring Form

Instructions: This form is used to submit WBC count and ANC monitoring information on multiple registry patients where treatment dispensation occurs on the same day. NOTE: DATA SUBMISSION TIMELINES MUST BE MET FOR ALL LISTED PATIENTS – (ie, form received by registry within 7 days of blood draw date for patients on weekly monitoring; 14 days for every two weeks monitoring; and 28 days for every 4 weeks monitoring).

- The Affiliated Healthcare Provider must provide Affiliated Pharmacist with complete WBC count and ANC test results according to individual monitoring schedule and valid prescription for each dispensation of Versacloz to meet monitoring requirements.
- The Affiliated Pharmacist can dispense Versacloz ONLY after receiving a completed WBC Count and ANC Monitoring Form with valid PRN, a valid prescription, and verifying the WBC count and ANC test result are within normal limits and timeframe according to Versacloz package insert.

Date:		**Pharmacy Name:**		**Pharmacy DEA or ID#:**			–							

WBC/ANC and Treatment Dispensation Information:

Patient Initials (FML)	**Patient SSN/PRN**	**Affiliated Healthcare Provider DEA or ID#**	**Blood Draw Date** (MM/DD/YYYY)	**Total WBC Count** (per mm^3)	**ANC (per mm^3)**	**Treatment Status After Today's Evaluation** **C=Continue** **T=Temporarily Discontinue** **P=Permanently Discontinue**	**Medication Dispense Date** (MM/DD/YYYY)	**Total Daily Dose** (mg/day)	**Acceptable to Dispense Treatment? Y=Yes N=No**	**Monitoring Schedule After Today's Evaluation**		
										Weekly	Every Two Weeks	Every Four Weeks

Pharmacist: Once this form is received from the Affiliated Healthcare provider this completed form should be mailed or FAXed to:
Versacloz Patient Registry
1818 Market Street, Suite 2350 **Fax: 1-877-798-0229**
Philadelphia, PA 19103

Alternatively, the data may be phoned into the Versacloz Patient Registry at 1-877-329-2256, or the information may be entered into the Versacloz database via the Internet at www.versaclozregistry.com

Versacloz™ Risk Evaluation and Mitigation Strategy (REMS)

Versacloz Patient Registry Information

General Overview | System Requirements | Registration and Monitoring Forms | HIPAA | Using the Registry FAQ | Versacloz Patient Registry Demo | Versacloz Patient Registry Login | Sign Up for the Versacloz Patient Registry

General Overview

Prescribing Information

- Prescribing Information
- Important Safety Information
- Download Adobe Acrobat

The Versacloz Patient Registry is a component of a Risk Evaluation and Mitigation Strategy (REMS) required by the United States Food and Drug Administration. Pursuant to this requirement Douglas Pharmaceuticals America Ltd. is required to collect laboratory data, patient identification information and investigate adverse events associated with Versacloz.

The Versacloz Patient Registry:

- Provides a database for WBC and absolute neutrophil count monitoring of patients treated with Versacloz to permit early detection of clozapine-induced leukopenia.
- Provides confidential registration and report process for patients treated with Versacloz.
- Provides ongoing updating of the Clozapine National Non-Rechallenge Masterfile with patients treated with Versacloz who become non-rechallengeable.

The Versacloz Patient Registry under the direction of the Versacloz Patient Registry Coordinating Center, includes a registry team, a professional toll-free call center at 1-877-329-2256, and a registry web-site.

The Versacloz Patient Registry team is composed of dedicated healthcare, registry, call center, administrative support and data management professionals.

The Versacloz Patient Registry Call Center is available 24 hours a day and 365 days a year to support all registry operations. Health care practitioners, pharmacist and patients may contact the call center with any questions related to the Versacloz Patient Registry. Health care practitioners and pharmacists may request registry materials directly through the call center.

Adverse Event Reporting

To report an adverse event please call 1-800-520-5568

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You may contact the Versacloz Patient Registry at 1-877- 329-2256 or at www.versaclozregistry.com. Please see full Prescribing Information, including BOXED Warning, for additional important safety information.

Jazz Pharmaceuticals

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
12/05/2013